

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Mental Health and Addiction Services _____

Regulation/Package Title: Service Certification and Prevention Service _____

Rule Number(s): 5122-25-01, 02, 03, 04, 05, 06, 07, and 08; 5122-26-01, 02, 03, 04, 06, 08, 08.1, 09, 11, 12, 13, 14, 15, 16, 16.1, 16.2, 17, and 18; 5122-29-12, 20, and 30; 3793:2-1-01, 3793:2-1-01.1, 3793:2-1-02, 3793:2-1-03, 3793:2-1-04, and 3793:2-1-07; Chapter 3793:4-1; and Chapter 3793:5-1.

Date: 5/5/2015 _____

Rule Type:

New

5-Year Review

Amended

Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. Please briefly describe the draft regulation in plain language.

Please include the key provisions of the regulation as well as any proposed amendments.

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As part of the consolidation between the Ohio Department of Mental Health and the Ohio Department of Alcohol and Drug Addiction Services (ODADAS), the Ohio Department of Mental Health and Addiction Services (Department) is consolidating the rules regarding the certification of services provided by mental health and alcohol and other drug addiction (AoD) service providers. As part of this consolidation the certification process described in OAC Chapters 3793:2-1, 3793:4-1, and 3793:5-1 have been combined with OAC Chapters 5122-25, 5122-26, and 5122-29. Not all former ODADAS rules pertaining to the certification of services in the OAC 3793 Chapters will be rescinded through this rule package, those changes will be forthcoming in a later filing. Additionally, some rule references made in the proposed amended rules are to renumbered chapter 3793 rules, which will be renumbered at the same time these rules are effective. (See the chart attached at the end of this section.)

Per R.C. Chapter 5119, provider service certification is required only of providers receiving funds from statutorily enumerated sources or those who voluntarily choose to be certified by the Department. Certification is not a requirement of operation; it is a requirement to receive certain types of funding.

The following changes are being proposed:

5122-25-01 - Updated to be current with statutory authority language, and has been reformatted for easier reading.

5122-25-02 – The rule is being amended to incorporate AoD programs from ODADAS rule 3793:2-1-01.1. A deemed provider is now required to notify the Department upon not renewing its accreditation on which the deemed status is based. Provisions for partial deemed status have been added to the rule for those occasions in which a provider is accredited in some services but not all. Paragraphs (H) through (M) incorporate provisions for granting deemed status formerly located in OAC 5122-25-03.

5122-25-03 – This is a new rule containing the certification procedure formerly found in 5122-25-04, but for non-deemed status providers only. The rule sets forth the contents of an application for certification, and the review and survey procedures for the Department to make a determination regarding the application.

5122-25-04 – This is an existing rule, but is being amended to be the certification procedure for deemed status providers only. The certification procedure for deemed and non-deemed providers is being separated into distinct rules in order to provide clarity of what is required of providers. The rule sets forth the requirements for a deemed status application, and the review and survey procedures for the Department to make a determination regarding the application.

5122-25-05 – This rule sets the provisions under which a certificate of services is issued. Paragraph (A) requires that for the enumerated services, a provider must have either an established history of providing the service or an accreditation as set forth in 5122-25-02. Paragraphs (B) and (C) concern the type of certificate issued: conditional, interim, and full; and the circumstances under which may be issued. Paragraphs (D) through (F) specify that certificates are site and service specific and may not be transferred. The rule also requires that a certificate be available for inspection and that a provider notify the Department of any changes that would affect the provider’s compliance with certification requirements.

5122-25-06 – This rule sets forth the waiver and variance procedures for the verification procedures. The rule is being amended only to change the usage of “agency” to “provider.”

5122-25-07 – This rule sets forth the conditions and procedures under which the Department may deny or revoke a certificate. The rule is being amended to add to the list of reasons for which a certificate may be denied, revoked, or terminated. The additional reasons being added to the rule include misuse of state or federal funds, falsifying data, and failing to discipline an employee who has abused or neglected a client. The rule now provides for a five year ban on providers who have their certification revoked by the Department and a three year ban on providers who have applications for new certification denied by the Department. In both cases, the provider may request written permission from the Department to re-apply early. The reasons for termination of a certificate now include a failure to reapply sixty days after being notified by the Department of the provider’s failure to file an application.

5122-25-08 – This rule sets forth the certification fee structure, it replaces the existing structure. The fee structure applies to all certified service providers, including AoD and prevention service providers who did not incur a fee prior to consolidation. Deemed status providers are exempt for all services for which they are accredited, but are required to pay the fees for those services which they are certified for but not accredited. Certification fees are due at the time of initial application or sixty days prior to the expiration of the current certification. Fees are based on the provider’s annual budget for the certified, but not accredited, services. Small providers with a budget under \$75,000, consumer operated services, and health home providers attempting to obtain accreditation pay no fees. Additionally, driver intervention program providers may exclude the cost of the housing provided as part of the program from the annual budget used to determine the fee.

5122-26-01 - Updated to be current with new statutory language.

5122-26-02 - Updated to be current with statutory authority language, and mirrors the applicability language of 5122-25-01.

5122-26-03 – This rule sets forth the requirements for provider leadership, and in the case of non-profit providers a specific governance structure. The rule is being amended to require that governing bodies provide for orientation for new members of the board and that the governing body shall approve the organization’s quality assurance plan. Government providers are also now required to have their board or governing body annually review the organizations quality assurance plan. The rule also now provides for greater flexibility in the naming of the provider’s executive director or chief executive position.

5122-26-04 - Updated to be current with new statutory language.

5122-26-06 – This rule sets forth the human resource program requirements for providers. Paragraph (C) is being amended to require that clinical services are provided under the supervision of one who is eligible to do so as set forth in OAC 5122-29-30 and who has demonstrated experience, competency, and training in the area being supervised. HR policies are now required to prohibit sexual harassment and include the specific safety procedures in OAC 5122-26-12, standards of acceptable behavior, standards for termination, and a requirement to inform employment applicants that the employer follows fair employment practices and respects confidentiality requirements in the hiring process. Providers who serve children and adolescents may no longer use employees who are under eighteen years of age for direct care positions, and all employees must meet the background requirements set forth in paragraph (E). Verification of professional credentials in employee files may now be electronic, and all personnel files now must include position description and other information regarding duties and qualifications. Providers must also document that employees have received and reviewed appropriate confidentiality regulations and the policies and procedures required by this rule.

5122-26-08 – This rule requires that access to and storage of client records and related information meet all federal and state regulations.

5122-26-08.1 - This rule was previously located in Chapter 5122-27, but is being moved as it more logically fits with the operation oriented rules. Added to the rule is the requirement that if a provider maintains an electronic health record, it must meet the requirements of federal and state law.

5122-26-09 – This rule requires that providers have a detailed plan for providing each service for which they are certified. The rule is being amended to include a description of the service at each level of care if appropriate.

5122-26-11 – This rule is being amended to remove the affiliation agreement requirement which is being phased out.

5122-26-12 – This rule sets forth environment requirements for the sites at which services are provided. Evacuation plans must now be posted and unvented kerosene or propane heaters are no longer permitted. Additionally, providers of halfway house, residential, or sub-acute detoxification services must meet minimum nutrition requirements for meals.

5122-26-13 – This rule sets forth the requirements and procedures for notifying the Department of incidents. In addition to statutory reference updates, the rule now requires that providers amend incident reports if new information reveals that an additional incident category is involved in a previously reported incident. The appendices associated with this rule have also been updated to reflect the consolidated nature of the Department.

5122-26-14 – This new rule sets forth the procedures for a voluntary closing, and allows for the orderly transition of clients to new service providers.

5122-26-15 – This rule sets forth the procedures for medication handling and dealing with drug theft. The rule is being amended to simplify training requirements for staff and require them to have basic and ongoing training regarding the safe and effective handling of medication. The rule now requires detailed policies and procedures for providers who allow clients to self-administer medication, including procedures for storing and accounting for client medications on-site. Providers are also required to have policies and procedures regarding employee theft of any medications at the provider site, the procedures shall include the reporting of the theft to the appropriate authorities and taking appropriate discipline against the employee.

5122-26-16 through 5122-26-16.2 – These rules set forth seclusion and restraint procedures and have been amended to update the definition of an advance directive; and to broaden the understanding of the role of trauma and be consistent with recent revisions to similar rules by the Department of Developmental Disabilities.

5122-26-17 – This rule sets forth standards regarding the accessibility and availability of services. The rule has been updated to use the term “Telecommunication Relay Services” (TRS), a broad definition of accessibility services that replaces the outmoded TDD/TTY devices. The rule has also been updated to require that no person be denied service based on their denial of a specific component of a service, so long as that is consistent with prevailing standards of care. The example used in the rule is a client may refuse medication but cannot be denied other aspects of services such as counseling.

5122-26-18 – This rule sets forth the rights of clients with regard to certified service providers and the grievance procedures to be adopted by providers. Each provider is required to have a written client rights policy and grievance procedure; which includes a retention period of at least two years for the grievance, the process used to remedy the grievance, and documentation of any circumstances that extended the response time for responding to the

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grievance. Each provider shall post the rights enumerated in this rule at each site under the provider's control, and shall make copies of the rights available at those sites not under the provider's control. The rule enumerates client rights separately for forensic and non-forensic clients, but in each case the enumerated rights have been developed based on past experience and through historical collaboration client advocate groups. Providers are required to explain the rights to each client at the beginning of their assessment or treatment; in the case of a crisis or emergency situation the provision of rights may be both verbal and only those rights immediately pertinent to the situation. The provider grievance procedure is detailed in the rule, generally requiring an obvious and manageable reporting procedure and a prompt acknowledgment of the grievance and resolution of the grievance. This rule is being filed as new, it replaces the existing rule and changes to both the content and the format of the rule are significant.

5122-29-12 – This is a new rule that defines driver intervention programs (DIPs). Previously DIPs were defined, and had their own certification process, in OAC Chapter 3793:4-1. However, the certification process is now combined with other OhioMHAS services and exceptions are provided in the certification requirements for those instances where DIPs will vary. The rule 5122-29-12 will serve as the “service” definition for DIPs, although they were continue to be referred to as programs.

5122-29-20 – This is a new rule that defines the prevention service. Previously, the prevention service had its own certification procedure set forth in OAC Chapter 3793:5-1; however with this rule package that chapter will be rescinded and the service certification rules in OAC Chapters 5122-25 to 5122-26 will apply to prevention providers. The new rule 5122-29-20 is an updated definition of the prevention service that is similar in format to other service definitions in OAC Chapter 5122-29. Per the rule, a prevention service is one which is intentionally designed to reduce the risk of or prevent the onset of a disorder and which is population focused and target to specific levels-of-risk. Certified prevention providers must provide one of the defined mandatory strategies, and one of the supporting strategies. Prevention providers must document some procedures and have an evaluation process, but are not required to keep records of all individuals who receive prevention service. Educational institutions and certain collation provided services are exempt from the requirements of certification.

5122-29-30 – The appendix to this rule is being updated to include prevention specific providers and the new marriage and family therapist trainee category.

OAC 3793:2-1-01, 3793:2-1-01.1, 3793:2-1-02, 3793:2-1-03, 3793:2-1-07, Chapter 3793:4-1, and Chapter 3793:5-1 are being rescinded as part of this package. Rule 3793:2-1-04 is

being rescinded as part of this package, but its substance is in rule 5122-28-03 which was reviewed as part of an earlier rule package.

The rules in OAC Chapter 3793:2-1 service certification rules specific to alcohol and other drug addiction programs, and are being consolidated into Chapters 5122-25 and 5122-26 as described below:

Consolidation of OAC 3793 Rules to OAC 5122	
Existing Rule	Consolidated Rule
3793:2-1-01 Program certification/licensure process	5122-25-03 to 05
3793:2-1-01.1 Deemed certification	5122-25-02
3793:2-1-02 Governing authority	5122-26-03
3793:2-1-03 Program administration	5122-26-03, 5122-26-04, 5122-26-06, 5122-26-12, 5122-26-14
3793:2-1-04 Quality assurance and improvement	5122-28-03
3793:2-1-07 Client rights and grievances	5122-26-18

The driver intervention program rules in Chapter 3793:4-1 are also consolidated into rules in Chapters 5122-25 and 5122-26 and the new rule 5122-29-12.

Consolidation of OAC 3793 Rules to OAC 5122	
Existing Rule	Consolidated Rule
3793:4-1-01 Driver intervention program certification process.	5122-29-12 and 5122-25
3793:4-1-02 Driver intervention program requirements.	5122-29-12 and 5122-26

The prevention program rules in Chapter 3793:5-1 are also consolidated into rules in Chapters 5122-25 and 5122-26 and the new rule 5122-29-20.

Consolidation of OAC 3793 Rules to OAC 5122	
Existing Rule	Consolidated Rule
3793:5-1-01 Prevention standards - certification process	5122-29-20 and 5122-25
3793:5-1-02 Prevention standards - governing authority	5122-29-20 and 5122-26
3793:5-1-03 Prevention standards - administration	5122-29-20 and 5122-26
3793:5-1-04 Prevention standards - quality assurance and improvement	5122-29-20 and 5122-28-03

3793:5-1-05 Prevention standards - provision of services	5122-29-20 and 5122-25
3793:5-1-06 Prevention standards - activity/consumer records	5122-29-20 and 5122-27
3793:5-1-07 Prevention standards - consumer rights and grievances	5122-29-20 and 5122-26-18

Rules to be renumbered concurrently with this rule package:

Existing Rule	Renumbered Rule
3793:2-2-01 Outpatient treatment program certification	5122-29-34
3793:2-3-01 Licensure to conduct an opioid agonist program	5122-29-35
3793:2-5-01 Residential treatment program certification	5122-29-36
3793:2-6-01 Detoxification program certification	5122-29-37

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

R.C. 5119.36

3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

If yes, please briefly explain the source and substance of the federal requirement.

No.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

Not applicable.

5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

R.C. 5119.36 requires the Department to establish certification standards and procedures, and fees, for service providers who fall under its regulatory authority. The standards in these rules are designed to insure the quality of care and the health and safety of those receiving services under programs funded and certified by the Department

6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

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Success of the service certification rules and program is measured by continued provider certification and compliance with these standards.

Development of the Regulation

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

If applicable, please include the date and medium by which the stakeholders were initially contacted.

The changes in this rule package have been discussed as part of the Department's Rules and Policy committee. The committee is composed of both individual stakeholders and trade groups representing both client and provider interests. Please see attached list for members.

The Committee met and discussed some or all of the rules in this package on:

January 24, 2014

February 28, 2014

May 23, 2014

June 27, 2014

July 18, 2014

August 22, 2014

September 26, 2014.

Additional input was sought regarding the prevention service through the Prevention Rules Committee, the Chemical Dependency Board Prevention Committee, the Prevention Roundtable, and the ADAPAO Think Tank on:

June 30, 2013

July 18, 2013

February 25, 2014

March 6, 2014

March 25, 2014- email request for feedback to Prevention Rule Committee

June 11, 2014

Prior to submitting the final version of these rules, the material was submitted to three separate stakeholder roundtables from March 13, 2015 to April 3, 2015. The roundtables are

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for Mental Health, Prevention, and Addiction; and are composed of stakeholders who are providers of services in those areas.

8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

Stakeholders have provided extensive input throughout this rule package. Chapter 5122-25 incorporates a new format for presenting certification requirements for deemed and non-deemed status that stakeholders provided input on to improve certification procedures. The new fee structure in 5122-25-08 is a departure from manner in which fees were previously calculated. Prior to consolidation, mental health service providers paid a certification fee, while those certified for alcohol and other drug addiction services by the former ODADAS did not pay a certification fee. The Department is required by Revised Code to assess a fee for certification of services, and the input of stakeholders from both the mental health services and AoD services prospective was vital in developing a fee structure that was equitable and rational. Chapter 5122-26 reflects stakeholder input that emphasized the integration of MH and AoD service providers.

The prevention service reflects an integrated approach, with the new rule reflecting only the definition of the service and combining prevention into the spectrum of services certified by OhioMHAS. The definitions and requirements of the rule are the direct result of the many stakeholder meetings conducted since June of 2013.

Stakeholder input outside of the standing stakeholder committees was sought for the updates to 5122-26-17, regarding the accessibility of services. Input was requested and received from Disability Rights Ohio and the Deaf Services Center; the updated language in paragraph (C) is a direct result of their assistance.

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

Not applicable.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

The rules reflect the results of long discussion amongst the Department and competing stakeholder interests. Some of the rules went through several distinct versions before a consensus was reached, including the rules regarding fees, access and availability, the prevention definition, client rights, and confidentiality.

11. Did the Agency specifically consider a performance-based regulation? Please explain. Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

Where possible the rules are outcome focused, the directive is to have policies and procedures for a certain subject or to meet certain standards. However, by necessity to protect health and safety or to insure quality of care, the rules are process focused.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The rules in this package apply only to service providers who are required to be certified by R.C. 5119.36. Where overlap may exist with other regulating authorities or professional bodies the Department has worked to insure the goal of insuring quality care is met. In particular, professional qualifications are left to be addressed by those authorities who regulate the professions, and service providers work to provide services within these programs within their "scope of practice" as dictated by their professional standards.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The Department already certifies providers of both MH and AoD services, and is in contact with the regulated community. The combined process and requirements will be communicated to the field as the rules become effective. Certifications that are current will continue in effect and providers will be given assistance and time to transition.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

- a. Identify the scope of the impacted business community;**
Any service provider as defined by R.C. 5119.36
- b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**
The adverse impact is fees for certification and the employer time required for compliance.
- c. Quantify the expected adverse impact from the regulation.**

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.

The changes to the certification fee structure are intended to be revenue neutral. Prior to consolidation AoD providers did not incur a fee for certification, while mental health providers did. Additionally, mental health providers who are accredited by third-party bodies and received deemed status paid no fees for those services covered by the deemed status. Fees are required by R.C. 5119.36 and the Department has worked with stakeholders to develop an equitable structure.

AoD providers will incur fees for the first time, however because all providers will be participating, the overall fees for mental health providers will decrease. It is even expected that some AoD providers will recognize a lower cost of overhead due to the streamlining taking place in the certification process and requirements.

The current fee structure is a two-part fee, a fee of \$5,000 for providers not currently certified by the department and a sliding scale fee based on the total funds the provider receives from its contract with a mental health board. The sliding scale fee ranges from \$180 to \$4200.

The new fee structure eliminates entirely the fee for new providers, and it simplifies the sliding scale fee. Additionally, the sliding scale fee is based on the provider’s budget for the certified services, and not the total funds received under contract from a mental health board. Providers with small certified services operations will likely fall within the first fee bracket and owe no fee for certification, and consumer operated services which are typically small in scope are specifically exempted from fees. Health home service operators are exempted from the fee structure during the period in which they are accumulating the required service time to become accredited. Driver intervention programs are allowed to exclude the cost of housing when calculating the budget and fee, as housing for these programs is not a clinical focus of the program and is not certified by the Department.

The Department has 409 certified mental health providers and 988 certified AoD sites under the current certification rules. The number of certified AoD sites will decrease as the focus under the new rules is on certifying providers rather sites, and fees are assessed per provider. During FY2014 the Department collected \$29,000 in certification fees. That number is expected to remain the same as the average fee amount will decrease but the number of providers paying the fee will increase.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The Department is required to certify service providers to insure the quality of care and the health and safety of those receiving care from providers receiving state and federal funds.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

No, the rules are intended to protect the health and safety of the clients and the size of the provider business is generally not a consideration in that area. However, the fee structure and other provisions with individual rules are intended to help smaller businesses where there is no impact to client health and safety.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

Penalties with regards to this rule package are a denial, suspension, or revocation of certification. The Department works with providers to insure that violations are presenting a risk to health and safety before moving forward with any disciplinary action.

18. What resources are available to assist small businesses with compliance of the regulation?

The Department's Office of Licensure and Certification can provide assistance to any provider.